



8405 '98 NOV 18 P2:16



November 15, 1998

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11/13/98

The Office of Special Nutritionals (HFS-450)
Center for Food Safety and Applied Nutrition
Food and Drug Administration
200 C. Street S.W.
Washington, DC 20204

Dear Sir/Madam:

This is a notification pursuant to 21 U.S.C. 343(r)(6) that Standard Process Inc., Palmyra, Wisconsin 53156-0904, is making the following statements:

- (1) Buckwheat contains rutin, a phytochemical of the flavonoid group and a powerful anti-oxidant, that protects the body against a variety of damaging oxidative toxins, especially those released by the body from mineral-fiber irritation. By itself, rutin is a more potent free radical quencher than either vitamin C or vitamin E.*
- (2) Anti-oxidants - rutin and quercetin help support the skin. Rutin and quercetin (another anti-oxidant found in buckwheat) strongly protect the skin from oxidative damage, even protecting the nerves within the skin.*
- (3) Soluble fiber and rutin found in buckwheat helps maintain the cardiovascular system. The soluble fiber in buckwheat can help maintain a proper balance between high and low density lipoproteins. Furthermore, rutin prevents the oxidation of low-density lipoprotein in artery walls. As an anti-oxidative, rutin also minimizes oxidative damage in red blood cells, especially to delicate cell walls (and to important fats embedded in those walls), and to essential oxygen-carrying hemoglobin. Rutin maintains the integrity of vein walls, thus preventing fluid leakage and swelling resulting from burns and radiation. It also helps to keep the blood thin, thus encouraging its free flow through the circulatory system, primarily in peripheral arterial systems.*
- (4) Quercetin, found in buckwheat, helps maintain orderly cell growth in breast and other tissues.*

97S - 0162

Also see docket 97S-0163

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STANDARD PROCESS INC. • 1200 WEST ROYAL LEE DRIVE • PALMYRA, WI 53156 • 414-495-2122 • FAX 414-495-2512 • 1-800-848-5061





These statements are made for a dietary supplement containing vacuum dried buckwheat leaf juice and seed, honey, bovine adrenal Cytosol Extract, ascorbic acid, oat flour, and calcium stearate. The name of the product is Cyruta-Plus®.

The information contained herein is accurate and Standard Process Inc. has substantiation that the statements are truthful and not misleading.

Sincerely yours,

Ann Holden
Standard Process Inc.

